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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/787,307	02/26/2004	Brian C. Case	1000-201	4350	
42715 7590 91/02/2009 BUCHANAN INTELLECTUAL PROPERTY OFFICE LLC P.O. BOX 700			EXAM	EXAMINER	
			STROUD, JONATHAN R		
PERRYSBURG, OH 43552-0700		ART UNIT	PAPER NUMBER		
			3774		
			MAIL DATE	DELIVERY MODE	
			01/02/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/787,307 CASE ET AL. Office Action Summary Examiner Art Unit JONATHAN R. STROUD 3774 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 September 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 37 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

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#### DETAILED ACTION

### Response to Arguments

1. Claim 36 has been cancelled. Applicant's arguments with respect to claim 37 have been considered but are moot in view of the new ground(s) of rejection. The office maintains that the earlier rejection was proper, and that the newly-amended claims remain inherent and obvious to one of ordinary skill in the art, but for the principles of expediency, a teaching reference is provided to prove the obviousness of the rejection.

## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be neadtived by the manner in which the invention was made.
- Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz 2003/0023303. or. in the alternative. further in view of Webler 2008/0125860.

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986).

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Palmaz discloses a valve with an orifice relative to the valve support structure and delivery apparatus that is equipped with radiopaque markers para. 0080 in order to allow the opening to be oriented in the proper direction para. 0080 upon deployment of the stent/valve body member 12.

Palmaz is silent on teaching that the imaging can be used to predict or control the delivery approach of the device, despite the fact that such properties of radiopaque implantable devices are well-known in the art. One of ordinary skill in the art would know that a radiopaque marker or stent element could assist in determining a delivery approach, or determine the orientation, as was listed in the previous rejection and above here "delivery apparatus that is equipped with radiopaque markers para. 0080 in order to allow the opening to be oriented in the proper direction para. 0080."

Webler teaches using visualization techniques and imaging techniques known in the art to assist device deliver, para. 0117, including the orientation of the catheter 200, the device itself, the sheath 117 and the like, further, para. 0192, "Wires or cords 3040 may then be used to position apparatus 2800 within mitral valve 3160 possibly with the use of imaging modalities, such as fluoroscopy, magnetic imaging angiography, doppler, echocardiography, etc., for the purpose of assisting in the delivery of the object.

It would have been obvious to one of ordinary skill in the art to modify Palmaz in view of the inherent or obvious nature of using an imagable device to determine a device's delivery profile and orientation, or in the alternative, to modify Palmaz in view of Webler, in order to use a known technique to assist the delivery of the object.

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#### Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/ Examiner, Art Unit 3774 /Thomas J Sweet/ Primary Examiner, Art Unit 3774